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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/622,719	10/18/2000	Hubert Locwenheim	24356	1261
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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC  
1420 FIFTH AVENUE  
SUITE 2800  
SEATTLE, WA 98101-2347

EXAMINER

LACOURCIERE, KAREN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/622,719

Applicant(s)

LOEWENHEIM, HUBERT

Examiner

Karen A. Lacourciere

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 28, 29, 31, 32, 34, 36-47, 55, 57, 58, and 62-66.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: Applicant's amendments are no in accordance with current amendment practice, for example, in claim 28, the amended version of the claims does not include markings to reflect all of the changes relative to the pending claims. Additionally, Applicant's proposed amendments broaden the scope of the claimed subject matter to generally treating hearing loss, instead of perceptice deafness, and therefore, would require further search and consideration.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, Applicant's proposed amendments would overcome the rejection of record of claim 55 under 35 USC 102(b) and the rejection of record of claim 44 under 35 USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: In response to the rejection of record under 35 USC 112, first paragraph, Applicant disagrees that the specification does not show that the resultant cells are not viable sensory cell, by pointing to the specification that provides statements to support that mature sensory cells do occur in knockout mice and that recovery of hearing is possible even with partial reduction of p27 Kip1. Applicant argues that the first and second Declarations provided by Dr Kil (of record) support that hair cells have been regenerated even with partial reduction of p27Kip1, including with antisense. This is not persuasive because Applicant is arguing the limitations of the claims as amended, however, the proposed claims amendments were not entered. Additionally, the experiments provided in the Declarations filed by Dr. Kil are not supported by the Application as filed. Applicant argues that in the claimed invention is directed to stimulating proliferation of supporting cells, thereby promoting the regeneration of functional sensory cells, thus the manner in which the sensory cells were destroyed does not matter, provided there are viable supporting cells that can proliferate. This is not found to be persuasive because Applicant is arguing a scope of the claims as amended, however, th proposed amendments have not been entered. Further, Applicant's arguments support the aspect of the rejection of record that states th claimed methods are very broad. Applicant argues that supporting cells need only proliferate to promote the growth of sensory cells, however, as discussed in the rejection of record, the claims would encompass many diseases that result in hearing loss wherein genetic or other causes result in hearing loss unrelated to p27Kip1 and, therefore, even with proliferation of supporting cells, treatment effects would not be realized.

In response to the rejection of record under 35 USC 112, first paragraph, Applicant argues that subject matter directed to p21Cip1 and p57Kip2 has been canceled and the pending claims are now directed to the use of antisense targeted to p27Kip1. Applicant argues that antisense inhibitors of p27Kip1 were known in the art (based on references of record in the case) and, therefore, the skilled artisan would recognize that the inventors were in possession of the invention at the time of filing. This is not persuasive because the arguemtns are directed to the amended claims, however, the proposed amendments have not been entered. Further, Although there are two examples of antisense to p27Kip1, both directed to the same species of mammalian p27Kip1, two antisense directed to one species of p27Kip1 would not be representative of the broad genus of antisense used in the claimed methods, because the genus of antisense and genes encoding mammalian p27Kip1 is highly variant and, therefore, antisense targeted to such would also be highly variant (with regard to structure, i.e. nucleotide sequence).

*antisense* *KIL 05-24-04*



KAREN A. LACOURCIERE, PH.D  
PRIMARY EXAMINER